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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,326	07/10/2003	Bastiaan Drichuys	PM0026 DIV	2824

7590

07/14/2006

Amersham Health, Inc.
101 Carnegie Center
Princeton, NJ 08540

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/617,326	Applicant(s) DRIEHUYS ET AL.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-69 and 80 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 64-69 and 80 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is cancer and a gene treatment preparation is administered, classified in class 424, subclass 9.2.
 - II. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is cardiac/pulmonary and a gene treatment preparation is administered, classified in class 424, subclass 9.2.
 - III. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is renal and a gene treatment preparation is administered, classified in class 424, subclass 9.2.
 - IV. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is hepatic and a gene treatment preparation is administered, classified in class 424, subclass 9.2.
 - V. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is cerebral and a gene treatment preparation is administered, classified in class 424, subclass 9.2.

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- VI. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is cancer and a pharmaceutical preparation is administered, classified in class 424, subclass 9.2.
- VII. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is cardiac/pulmonary and a pharmaceutical preparation is administered, classified in class 424, subclass 9.2.
- VIII. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is renal and a pharmaceutical preparation is administered, classified in class 424, subclass 9.2.
- IX. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is hepatic and a pharmaceutical preparation is administered, classified in class 424, subclass 9.2.
- X. Claims 64-69, drawn to a method of evaluating the efficacy of targeted drug therapy wherein the treatment condition is cerebral and a pharmaceutical preparation is administered, classified in class 424, subclass 9.2.
- XI. Claim 80, drawn to a method of preparing a gas container, classified in class 428, subclass 34.1 +

Note: Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct from one another because each group is directed to evaluating a condition that is neither anticipated or rendered obvious by another group. Also, the groups are distinct because a pharmaceutical preparation is different from a gene treatment preparation. In particular, a pharmaceutical preparation is generally administered for medicinal purposes while a gene preparation is typically administered to alter/modify some gene activity. Furthermore, Group XI is different from all the other groups because it is directed to a method of preparing a gas container that is unrelated to the groups directed to a method of evaluating the efficacy of a targeted drug.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES

4. Claims 64-69 and 80 are generic to the following disclosed patentably distinct species wherein a gene treatment preparation or a pharmaceutical drug is utilized. The

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species are independent or distinct because a gene treatment preparation has distinct properties from a pharmaceutical. In particular, a gene treatment preparation is used in procedures wherein the aim is to alter some genetic matter whereas a pharmaceutical preparation is typically administered to a subject for medicinal purposes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

8. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.


10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

July 10, 2006